


II. IN THE CLAIMS

Please cancel claims 7, 9-40, 42-48, 50, 60, 61, and 73-75, which are drawn to non-elected inventions without prejudice to Applicants' right to pursue the subject matter of the canceled claims in one or more continuation or divisional applications. In compliance with proposed 37 C.F.R. § 1.121, a complete list of all claims are presented below. Claims 62, 67, and 76 are amended and are supported by the specification. Newly added claims 82-88 are fully supported by the specification as explained in Section III Remarks. No new matter is added.

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62. (Amended) A pharmaceutical composition comprising as active principle biologically active isolated Tat protein, fragments thereof and/or mutants in combination with suitable excipients and/or diluents, wherein said Tat protein, fragments and/or mutants, ~~are capable of~~: 1) ~~entering~~ enter activated endothelial cells or dendritic cells at concentrations up to 10 nM and 2) ~~performing~~ perform at least one action selected from the group consisting of the following actions: i) ~~activating~~ activate the proliferation, migration and invasion of Kaposi's sarcoma (KS) cells or cytokine-activated endothelia cells; ii) ~~activating~~ activate virus replication when added to infected cells as measured by a) the rescue of Tat-defective proviruses in HLM-1 cells after the addition of exogenous protein and/or b) the transactivation of HIV-1 gene expression in cells transfected with HIV-1 promoter-reporter plasmid; and iii) ~~indueing~~ induce in mice the development of KS-like lesions in the presence of angiogenic factors or inflammatory cytokines.

63. (Previously Added) The pharmaceutical composition according to claim 62, wherein Tat, in its purified, non-aggregated and non-oxidized form, is lyophilized for storage and resuspended in a biologically acceptable fluid for use.

64. (Previously Added) The pharmaceutical composition according to claim 62, wherein said composition is a vaccine for use in the prophylactic and/or therapeutic treatment of AIDS, tumors, syndromes and symptoms associated with HIV infection.

65. (Previously Added) The pharmaceutical composition according to claim 62, wherein Tat has the sequence identified as SEQ. ID. NO 2.

66. (Previously Added) The pharmaceutical composition according to claim 62 in a form suitable for administration selected from the group consisting of mucosal, nasal, oral, vaginal, rectal, intramuscular, subcutaneous, intradermal systemic and local administration.

67. (Amended) The pharmaceutical composition comprising as active principle biologically active isolated Tat protein, fragments thereof and/or mutants in combination with suitable excipients and/or diluents, wherein said Tat protein, fragments and/or mutants 1) enter activated endothelial cells or dendritic cells at concentrations up to 10 nM and 2) perform at least one action selected from the group consisting of the following actions: i) activate the proliferation, migration and invasion of Kaposi's sarcoma (KS) cells or cytokine-activated endothelial cells; ii) activate virus replication when added to infected cells as measured by a) the rescue of Tat-defective proviruses in HLM-1 cells after the addition of exogenous protein and/or b) the transactivation of HIV-1 gene expression in cells transfected with HIV-1 promoter-reporter plasmid; and iii) induce in mice the development of KS-like lesions in the presence of angiogenic factors or inflammatory cytokines and wherein said Tat is obtained by a process comprising a purification step performed under conditions to prevent is oxidation and aggregation.
68. (Previously Added) The pharmaceutical composition according to claim 67, wherein said purification step is performed by heparin affinity chromatography.
69. (Previously Added) The pharmaceutical composition according to claim 68, wherein said purification step is followed by storage of the Tat protein in lyophilized form and its resuspension in a degassed buffer.
70. (Previously Added) The pharmaceutical composition according to claim 67, wherein said composition is a vaccine for use in the prophylactic and/or therapeutic treatment of AIDS, tumors, syndromes and symptoms associated with HIV infection.
71. (Previously Added) The pharmaceutical composition according to claim 67, wherein Tat has the sequence identified as SEQ. ID. No 2.
72. (Previously Added) The pharmaceutical composition according to claim 67, in a form suitable for administration selected from the group consisting of mucosal, nasal, oral, vaginal rectal, intramuscular, subcutaneous, intradermal systematic and local administration.
73. (Canceled)

74. (Canceled)
75. (Canceled)
76. (Amended) Biologically active isolated Tat protein, fragments thereof and/or mutants, wherein said Tat protein, fragments and/or mutants ~~are capable of~~: 1) ~~entering~~ enter activated endothelial cells or dendritic cells at concentrations up to 10 nM and 2) ~~performing~~ perform at least one action selected from the group consisting of the following actions: i) ~~activating~~ activate the proliferation, migration and invasion of Kaposi's sarcoma (KS) cells or cytokine-activated endothelia cells; ii) ~~activating~~ activate virus replication when added to infected cells as measured by a) the rescue of Tat-defective proviruses in HLM-1 cells after the addition of exogenous protein and/or b) the transactivation of HIV-1 gene expression in cells transfected with HIV-1 promoter-reporter plasmid; and iii) ~~inducing~~ induce in mice the development of KS-like lesions in the presence of angiogenic factors or inflammatory cytokines.
77. (Previously Added) The Tat protein according to claim 76, wherein Tat, in its purified, non-aggregated and non-oxidized form, is lyophilized for storage and re-suspended in a biologically acceptable fluid for use.
78. (Previously Added) The Tat protein according to claim 76, wherein Tat in its purified, non-aggregated and non-oxidized form, is lyophilized for storage and re-suspended in a biologically acceptable fluid for use as a vaccine.
79. (Previously Added) The Tat protein according to claim 76, wherein Tat has the sequence identified as SEQ. ID. NO. 2.
80. (Previously Added) The Tat protein, fragments thereof and/or mutants, as defined according to claim 76, for preventing or treating AIDS, tumors and syndromes and symptoms associated with HIV infection.
81. (Previously Added) The Tat protein, fragments thereof, and/or mutants, as defined according to claim 79, for preventing or treating AIDS, tumor sand syndromes associated with HIV infection.

82. (New) A vaccine composition comprising an isolated biologically active Tat protein, or biologically active fragment or mutant thereof, wherein said biologically active Tat protein, fragment or mutant is in a non-aggregated and non-oxidized form and is in an amount effective to induce an immune response against said biologically active Tat protein, fragment or mutant in a subject.
83. (New) The vaccine composition of claim 82 wherein said biologically active Tat protein has an amino acid sequence of SEQ ID NO.: 2.
84. (New) The vaccine composition of claim 82 or 83 which is lyophilized.
85. (New) The vaccine composition of claim 84 which is resuspended in a pharmaceutically acceptable fluid for use.
86. (New) The vaccine composition of claim 82 or 83 which is in a form suitable for mucosal, nasal, oral, vaginal, rectal, intramuscular, subcutaneous, intradermal, systemic or local administration.
87. (New) The vaccine composition of claim 82 or 83 wherein said biologically active Tat protein or fragment or mutant thereof is purified using a process that prevents oxidation and aggregation.
88. (New) The vaccine composition of claim 87 wherein said biologically active Tat protein or fragment or mutant thereof is purified by heparin affinity chromatography.
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